JUN 2 5 2004

Sicel Technoiogies, Inc.

3800 Gateway Centre Boulevard • Suite 308 • Morrisville, NC 27560 • (919) 465-2236 • FAX (919) 465-0153

K040687

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

Submitter:

Sicel Technologies, Inc.
3800 Gateway Centre Blvd.
Suite 308
Morrisville, NC 27560

Contact: Tammy B. Carrea, Director Regulatory Affairs
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Prepared: March 15, 2004

Common or Usual Name:	Patient Radiation Dosimeter
Proprietary Name:	OneDose Patient Dosimetry System
Classification Name:	Accelerator, Linear, Medical
Manufactured By:	Sicel Technologies, Inc. 3800 Gateway Centre Blvd. Suite 308 Morrisville, NC 27560 Phone: (919) 465-2236 Fax: (919) 465-0153

Predicate Device(s): K949687

Thomson Nielsen
K010472 and K032725
TN-RD-50 and Autosense Wireless Dosimetry System

Sun Nuclear
K021463 and K011332
rf-IVD and rf-IVD PC version

Device Description:

The OneDose Patient Dosimetry System consists of the following components and accessories: (1) disposable, single use, pre-calibrated radiation dosimeters, (2) a hand held, battery powered reader, and (3) a reader calibration test strip. The dosimeters use a MOSFET, metal oxide semiconductor field effect transistor as a sensing mechanism. The dosimeters are inserted into the Reader and zeroed, then positioned onto a patient. The dosimeters are small and have no wires. They have a medical grade adhesive and liner on the back. The liner is removed and the adhesive side of the dosimeter is adhered to the patient. Following radiotherapy, the dosimeters are removed from the patient, re-inserted into the Reader, and the patient's dose is read and reported by the Reader. The patient's records are stored on the dosimeter for future reference and in the Reader's memory.

Indication for Use:

The OneDose Patient Dosimetry System is intended to measure a patient's dose during radiotherapy applications.

Comparison with Predicate Device:

The OneDose and the Thomson Nielsen Patient Dose Verification System (K010472, K032725) and the Sun Nuclear RF-IVD System (K011332 and K021463) have the same intended use and similar indications, principles of operation and similar technological characteristics. Both devices are intended for patient dosimetry. The Sun Nuclear device and OneDose are battery powered. The Thomson Nielsen device and the OneDose use a MOSFET as the sensing mechanism. The only technological differences between the OneDose and its predicates are: (1) the OneDose is not wired to a patient; (2) the OneDose is pre-calibrated; and (3) the OneDose is a disposable, single use device.

These differences do not present any new issues of safety or effectiveness because the OneDose is safer for the patient since there are no cables wired to the patient and the OneDose is more convenient for the user since it is pre-

calibrated and disposable. K040687

The OneDose, while pre-calibrated, is calibrated for thermal fluctuations in a method similar to the Sun Nuclear device which is also provided by the manufacturer with correction factors built in. The OneDose is calibrated at the factory using the same method as the Thomson Nielsen for evaluating radiation units/volts except that the OneDose is calibrated under controlled conditions at the factory and the Thomson Nielsen device must be calibrated by the user. The factory calibration procedure is described in sufficient detail within the 510(k) to demonstrate the methods used to assure calibration and the data contained with the performance data section demonstrates that calibrated devices perform within the stated performance specifications of the labeling.

The OneDose is a single use dosimeter and the used device may be archived or thrown away versus continuous re-use of dosimeters like with other dosimetry systems. Data within the 510(k) demonstrates that the adhesive used with the OneDose dosimeter for adhering to skin is a safe, medical grade material found to be non-toxic, a non-sensitizer, and a non-irritant.

Thus, the OneDose is substantially equivalent to the Thomson Nielsen Patient Dose Verification System (K010472, K032725) and the Sun Nuclear RF-IVD System (K011332 and K021463).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2004

Ms. Tammy B. Carrea
Director, Regulatory Affairs
Sicel Technologies, Inc.
3800 Gateway Centre Boulevard
Suite 308
MORRISVILLE NC 27560

Re: K040687
Trade/Device Name: OneDose Patient Dosimetry System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: June 1, 2004
Received: June 2, 2004

Dear Ms. Carrea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K040687

Device Name: OneDose Patient Dosimetry System

Indications for Use:

The OneDose Patient Dosimetry System is intended to measure a patient's dose during radiotherapy applications.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040687